Gerraughty depo

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

ROBIN WHITE, et al. Plaintiffs, vs. Beckwith Hogan METABOLIFE INTERNATIONAL, INC. Defendant.	)	
	)	Case No. C-1-01-356
	)	Judge Sandra S.
	)	Magistrate Timothy S.
SHERRI COX, et al. Plaintiffs, vs. Beckwith Hogan METABOLIFE INTERNATIONAL, INC. Defendant.	)	
	)	Case No. C-1-01-643
	)	Judge Sandra S.
	)	Magistrate Timothy S.
CYNTHIA A. JOHNSON, et al. Plaintiffs, vs. Beckwith Hogan METABOLIFE INTERNATIONAL, INC. Defendant.	)	
	)	Case No. C-1-01-676
	)	Judge Sandra S.
	)	Magistrate Timothy S.
BARBARA J. BRADLEY, et al. Plaintiffs, vs. Beckwith Hogan METABOLIFE INTERNATIONAL, INC. Defendant.	)	
	)	Case No. C-1-01-809
	)	Judge Sandra S.
	)	Magistrate Timothy S.

DEPOSITION OF

ROBERT J. GERRAUGHTY, PH.D.

Taken at the Clarion Inn and Convention Center
211 Southeast Walton Boulevard
Bentonville, Arkansas 72712
April 4, 2003
8:30 a.m.

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- appearances continued on next page -

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Gerraughty depo

S T I P U L A T I O N S

IT IS HEREBY STIPULATED AND AGREED by and between counsel for the parties hereto that the deposition testimony of Robert J. Gerraughty, Ph.D., shall be taken before Blake Greenway, certified court reporter and notary public, at the above-captioned time and place, and may, if necessary, be used as evidence in the above-captioned matters.

Said deposition is taken pursuant to the Federal Rules of Civil Procedure. Objections except as to the form of the question and responsiveness of the answer are reserved until the time of trial.

P R O C E E D I N G S

(The witness was sworn.)

Whereupon,

ROBERT J. GERRAUGHTY, PH.D.,

Having been first duly sworn, testified as follows:

DIRECT EXAMINATION

BY MR. ERNY:

Q Good morning, sir.

A Good morning.

Q Can you state your name for the record, please?

A Yes, Robert J. Gerraughty.

Q What is your current address, sir?

A 1 Bruton Lane, (spelling) B-R-U-T-O-N Lane, Bella Vista, Arkansas 72715.

Q Is that an office or a home address?

A That's a home address. I have my office in my home.

Q What is your date of birth, sir?

A 8/30/28.

Q We share a birthday.

A Hmm?

Q We share a birthday.

A Oh, do we?

Q We do.

A Okay.

Q Other than the office that you have at home, which I

understand is your consulting business, right?

A Yes, that's correct.

Q Are you employed in any other capacity?

A No, I'm retired in other capacities.

Q How long ago did you retire?

A 1991, the end of 1991.

(Whereupon, Exhibit Number 1 was marked for identification.)

Q Dr. Gerraughty, I'll show you what the court reporter has marked as Deposition Exhibit Number 1, and I will tell you that this is the curriculum vitae, or as you have set forth, the biographical data that was provided with your expert report. Is this your current CV?

A There may be a few more things that I've added since this was done in January of 2002, and I haven't revised it recently.

Q This is the current version in terms of revisions, but there may have been things that you've done that you haven't yet put on there?

A Yes, that's correct.

Q What kind of things have you done that have not made it on to this?

A I've done similar consulting for companies, for drug companies, and I've given a lecture, I think, maybe two

lectures since this, at a symposium.

Q What were the lectures on?

A Good manufacturing practices, in general.

Q Were they good manufacturing practices as they relate to pharmaceutical manufacturers?
A Yes, they were.
Q You previously discussed some consulting for drug companies. Have you done any consulting for any dietary supplement companies?
A Not since this report, but I have in the past.
Q Who have you consulted for in terms of the dietary supplement companies in the past?
A I've consulted in Saudi Arabia for one. I've consulted for several in the United States over the years. Some of them are listed on here. Several of the companies that I've consulted for have dietary supplements, but they also have drugs too.
Q Has your consulting with those companies concerned the drug side or the dietary supplement side?
A Both.
Q What kind of consulting have you done for them?
A Basically, review their good manufacturing practices and their compliance with DSHEA.
Q I'm sorry, I didn't hear that last acronym.
A DSHEA, Dietary Supplement Health Education Act.

Q Can you point out in your CV those places that you've consulted with that manufactured both drugs and dietary supplements?
A Yes, I'll have to look at them.

Q If you look on page 9, it lists your consultancies.
A Okay.
MS. ABARAY: It looks like it's page 7.
A Metabolic -- well, wait a minute. That's the previous page. Number 6 would involve a little bit of that.
Q Number 6, where it says, "Consultant to Government of India on pharmaceutical formulation, formularies and drug regulation?"
A Yes.
Q In 1962 and 1963?
A Yes.
Q And it's your testimony that this also involves consulting on dietary supplements?
A There were some that would be classified today as dietary supplements, yes.
Q What was it that you consulted on that today would classified as a dietary supplement?
A I can't tell you the exact things. It's been so long ago.
Q Okay.

A Metabolic Products Corporation involved a dietary supplement used to treat urinary problems.
Q What was that dietary supplement?
A I can't remember the name of it.
Q The CV says that you've been a general consultant to Metabolic Products Corporation from 1966 to the present.

Is that accurate?
A Yes, they still call me on occasion, but I don't do much work for them, haven't done much work for them in the last five or six years.
Q The dietary supplement product that you consult with them on, does that involve ephedra?
A No.
Q Does it involve caffeine?
A No.
Q And you say it has something to do with urinary?
A Yes, urinary problems.
Q And you can't remember the name of the product?
A No, because I haven't done any work with them on that product recently.
Q It is a dietary supplement, though?
A Yes, it was listed as a dietary supplement. Let me look. Spimaco Company in Saudi Arabia, which is number 36. They have vitamins and vitamin combinations with minerals.
Q This is the Saudi Arabia consulting that we talked

about earlier?
A Yes.
Q Do any of their products contain herbal substances?
A Yes.
Q What herbal substances are in their products?
A They have a number. I can't recall from memory exactly which ones they were. The main ones that I dealt

with were vitamins and minerals. They did have some plant materials in some of their products.

Q Did any of the plant materials consist of ephedra?

A No.

Q How about caffeine?

A I'm not sure.

Q Does Spimaco import product into the United States?

A I don't know whether they do or not. They've been in the process of trying to get permission, or trying to get clearance, to ship products to the U.S. They ship to other Middle Eastern countries.

Q As far as shipping to other Middle Eastern companies, that would not be covered by DSHEA, would it?

A No.

Q Does your consultancy with Spimaco involve compliance with DSHEA?

A Yes, because the vitamins come under DSHEA and the minerals.

Q Even though they only ship in the Middle East?

A I'm not sure they only ship in the Middle East. That's my problem.

Q So you're not sure that they import into the United States?

A I'm not sure, no. I don't know whether they've begun or not.

Q Would it be fair to say that if they don't import into the United States, that DSHEA or the reach of DSHEA

doesn't reach them?
A I would think that would be the case, yes.
Q Any others?
A There's a lot of them on here, for example, Abbott Laboratories, Lilly, they have some products that are dietary supplements, but I didn't consult with them specifically.
Q I understand that, and that's a good point. I'm looking for the consultancies that you've been involved with that are listed here or that maybe haven't made it on your CV that involve dietary supplements, because I'm looking for your experience in the dietary supplement area.
A In those cases, I have to say, in some cases, I spent more time on dietary supplements, and some cases I spent more time on drugs.
Q And you're talking about the cases that we've talked

about already, right?
A I'm sorry, I don't understand.
Q That was a bad question. When you said, in those cases, some of it is more for dietary supplements, and some of it is more for drugs, are you talking about your consultancies with Abbott and Lilly?
A Yes, and other companies, too.
Q What dietary supplements have you been involved, other than what we've talked about already, either with Abbott or Lilly or these other companies that you're

telling me about. What dietary supplements have you consulted on?

A Mostly on vitamins and minerals, and I would say that would be mostly it. In the case of Spimaco, it was more natural products, so plant drugs.

Q But that also involved vitamins, and vitamins and minerals?

A Yes.

Q Have you ever consulted with a company with regard to ephedra or a caffeine product?

A No.

Q Have we gone through, now, all the consultancies that you've been involved with dealing with dietary supplements?

A I believe so.

Q I see from the first page of this that you have a Ph.D in pharmaceutical sciences?

A Yes.

Q What is pharmaceutical sciences?

A Well, there are several pharmaceutical sciences. Usually, at the lower level, the Bachelor's and Master's, you specialize in one of them. In the case of the Ph.D. from the University of Connecticut, you take pharmacology, you take manufacturing pharmacy, you take a broad -- although, I majored in manufacturing pharmacy, I covered some of the other areas, too, and course work for that.

Q Are you talking about in your undergraduate days?

A No, I'm talking about graduate school. I took some in pharmacology. I had to take some other courses in pharmacology, statistics, things like that.
Q Your Ph.D. in pharmaceutical sciences, is that equivalent to a Ph.D. in pharmacology?
A I would say equivalent to a Ph.D. in pharmacy.
Q I understand that, at least in the past, you've been a licensed pharmacist?
A Yes, I have.
Q Are you still currently licensed?
A No, I'm on retired status as far as being a registered pharmacist in several states.
Q Did you go on to retired status in 1991?

A No, I went earlier than that, because I was in teaching and administration.
Q In the past, had your pharmacy licenses in any state ever been denied?
A No.
Q Ever been revoked?
A No.
Q Have they ever been suspended?
A No.
Q Other than the pharmacy licenses that you have held, have you ever been licensed in any other professions?
A No.
Q Other than the consulting in which you are engaged

in presently, are you involved in any other activities such as teaching and things of that nature?

A Yes, I'm an adjunct facility member at the University of Rhode Island, and I usually give a series of lectures on manufacturing pharmacy and good manufacturing practices just about every year.

Q To whom are those lectures given?

A Undergraduate and graduate students in pharmacy at the University of Rhode Island.

Q Is there a College of Pharmacy at the University?

A Yes.

Q So you give it to students that reside or

matriculate in the College of Pharmacy?

A Yes, that's correct. They do have some other people who sit it on them, but I don't know why.

Q When you teach these, how many days a year would it consist of?

A Three or four.

Q On the first page of your CV, you list some additional training underneath your education, which goes on for this first page here. At least as far as I understand that, none of it seems to be in the food and drug field. Is that correct?

A Yes, because that would be picked up somewhere else. That's probably true.

Q I understand, okay. On page 4 of your CV under the heading Positions Held, the last entry there indicates that

you've been a Consultant on Pharmaceutical Issues from 1958 to the present. Do you see that there?
A No. Page 4?
Q Page 4, right above Military Service.
MS. ABARAY: He's on page 4 of the fax.
Q I'm looking at page --
A Oh, okay, I'm getting confused by that.
Q I'm going from the actual CV page numbers, so there you go. Do you see the --
A Yes, I do.

Q This would refer to the consultancies which we've talked about earlier, right?
A Some of them, yes.
Q When you're talking about pharmaceutical issues, you're talking about manufacturing, formulations, stability of pharmaceutical products, correct?
A Yes, and good manufacturing practices.
Q When you talk about pharmaceutical products, you're talking about prescription pharmaceutical products and over-the-counter products?
A Both.
Q On the next page of your CV, I see that you were the Director of the University of Rhode Island Training Course for the U.S. Food and Drug Inspectors?
A That's correct.
Q What did you do as the Director of that training

course?
A Organize getting faculty to teach the course. Basically, it was between three and four weeks. It was three weeks for a while, and then it was a four-week course later. It would be lining up faculty, setting up study plans, and scheduling lectures, and I gave a large portion of the lectures in the course myself.
Q And it would be to people that were employed for the U.S. Food and Drug Administration?

A Food and Drug Administration investigators, yes. Some of them were pharmaceutical investigators, and some of them were food investigators.
Q You list that you did that during the time period of about 1963 to 1972, 1990 and 1992, is that right?
A That's correct.
Q Were you paid for doing this?
A Yes, but I had to limit what I could take, because I was working for the University. They gave me permission. It was during the summer that the courses were taught.
Q Who paid you?
A The University did. They paid the University and the University paid me a stipend, mainly, not for the teaching, but for the administration of the course.
Q Would the University, then, have a contract or receive a grant from the United States government to pay for your services?
A Yes.

Q If you could turn to the next page of your CV, this actually talks about grants and contracts that you have received?
A Yes.
Q Number 3 lists an annual FDA contract to conduct Training Course for Drug Inspectors, do you see that there?
A Yes.

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Q And this also has a date period or time period from 1963 to 1972?
A Yes.
Q And that matches up, at least, with that first time period on the previous page where you were the Director?
A I think so, yes.
Q Does this grant or contract refer to that training course that you gave?
A That would be for those training courses, yes.
Q And at least as you've described them on page 6, it was a training course for drug inspectors, right?
MS. ABARAY: Are you asking as opposed to food?
MR. ERNY: Yes.
Q There's no mention of any food inspectors in here.
A It was mainly drug inspectors, so that's why I said that.
Q And that would be true with the other time periods, where you were the Director of the University of Rhode

Island Training Course. That dealt mainly with drug inspectors, correct?

A Yes. I would assume so, yes.

Q Well --

A Yes, it was.

Q Okay. Have you ever done any consulting work for

anybody in the food industry?

A Specifically, in the food industry, I've done some consulting for Ross Labs. They have infant formulas and so forth.

Q Are infant formulas treated as foods?

A Yes, most of them are.

Q Anybody else?

A I can't recall. I can't recall whether any of those involved foods or not.

Q The consulting that you did for Ross Labs., what did that involve?

A I reviewed some documents for them and made some recommendations for good manufacturing practices.

MS. ABARAY: Does food include cosmetics, when you're asking him?

MR. ERNY: I didn't intend it to do that.

Q What GMP's did you utilize in consulting with them?

A I'm sorry, I don't understand.

Q Well, if I understand, the regulatory scheme in the United States has current good manufacturing regulations as they pertain to foods, correct?

A Yes.
Q And then in a separate set of regulations, there are current good manufacturing practices for over-the-counter products, correct?

A Basically, they don't divide, but they do divide within. Yes, I would say that's a reasonable statement.
Q Then there's still yet another set of current good manufacturing practices for pharmaceutical products?
A Prescription drugs.
Q Right, right, correct. So when you consulted with Ross Labs, were you utilizing the current good manufacturing practices set out in the federal regulations for food products?
A Yes.
Q So you have some familiarity with them?
A Yes.
Q Let's change gears on you a little bit.
A Okay. Are we done with this?
Q For right now we are, yes. Actually, I lied. I'm not going to change gears. We talked previously about some consultancies that you've done for some dietary supplement manufacturers, in particular, companies that had vitamins and mineral products, and the one company that had some plant materials. What set of regulations did you rely upon when you consulted with those companies?
A Basically, the DSHEA.

Q I'm going to refer to that as DSHEA, okay?
A Okay.
Q Does DSHEA actually set forth current good

manufacturing practices?
A No, they leave most of them up to the individual company, but they do require that they be safe. The only thing that's different is they don't require them to be effective. They would like them to be effective, but they don't require it.
Q You said that DSHEA requires, I think your words were -- actually, I can't recall, but you said it requires them to establish their own manufacturing practices?
A It requires them to meet standards of safety and non-adulteration.
Q Let me just state for the record that -- let me do it this way. We'll get back to this.
(Whereupon, Exhibit Number 2 was marked for identification.)
Q Dr. Gerraughty, let me show you what the court reporter has marked as deposition Exhibit Number 2. That's the deposition notice, and in the deposition notice, we've asked you to bring your file and you have in turn have brought your file and showed it to me. Is that right?
A That's correct. I did not bring all of the depositions and all the paperwork. It's a huge amount.
MR. ERNY: Let's go off the record.
(Whereupon, there was a discussion off the

record.)

MR. ERNY: While we were off the record, Ms. Abaray and I had a discussion with regard to Dr. Gerraughty's file, and we've agreed to do two things. First of all, Dr. Gerraughty is going to compile a list of the other material that he has, which he has not brought to the deposition, and provide that list to Ms. Abaray who will provide it to me, and we've also agreed that the court reporter will take the file, which Dr. Gerraughty has brought with him to the deposition, and copy the complete contents of that. That copy will be marked as Exhibit Number 3 to the deposition. Is that accurate, Ms. Abaray?

MS. ABARAY: That's fine.

THE DEPONENT: May I get a clarification, please?

MR. ERNY: Yes.

THE DEPONENT: Some of them that were sent to me didn't deal with GMP issues at all, and I didn't, other than open them up and find out they're going to be about something else, I didn't really review them.

MR. ERNY: Would it be possible on that list if, for example, you got a deposition, and you just flipped through and found that it didn't deal with

GMP's, you just wrote, does not deal with GMP's?

THE DEPONENT: Yes, I can to that.

MR. ERNY: Off the record, again.

(Whereupon, there was a discussion off the record.)

BY MR. ERNY: (Resuming)

Q Dr. Gerraughty, one of the things in your file, and I'm going to give it to you, but I'm not going to separately mark it, is a copy of Public Law 103-417, the Dietary Supplement Health and Education Act of 1994. Can you point out to me where in DSHEA it provides that the manufacturers are individually responsible for establishing their own manufacturing practices to ensure purity and safety of their products?

A I just got this this morning from Janet.

MS. ABARAY: He had asked for another copy.

MR. ERNY: Let me do it this way, then. Let me get this marked as Exhibit 4.

(Whereupon, Exhibit Number 4 was marked for identification.)

Q Dr. Gerraughty, the court reporter has marked as deposition Exhibit Number 4 the Preliminary Review of Documents in this matter. This is the report that you have provided to Ms. Abaray following your review of the materials, right?

A Yes, that's correct.
Q If you turn to page 2 of that, the second page of that report, you say in the second paragraph, "While cGMP regulations have not been finalized, DSHEA provides that manufacturers are individually responsible for establishing their own manufacturing practices to ensure purity and safety of their products." Do you see that there?
A Yes, I do.
Q Is that the standard by which you measured Metabolife's conduct?
A Yes.
Q Where in DSHEA do you find that proviso, that the manufacturers are individually responsible for establishing their own manufacturing practices to ensure purity and safety of their products?
A I can't tell you now, because I don't have my copy. I was unable to find my copy. That's why I asked her to bring me another one.
Q Okay, could you look at the copy that Ms. Abaray brought for you and pull that out for me.
MS. ABARAY: This copy only shows the amendments. You need the whole statute.
THE DEPONENT: Yes, this is only the amendments, so I can't from this.
MR. ERNY: Well, actually --

MS. ABARAY: This is G that gets added on to 21 U.S.C. 342, but you need all of 21 U.S.C. 342 to see the rest of the sentence.

MR. ERNY: Actually, that's the public law that enacts DSHEA, so this amends that statute to add the Dietary Supplement Health and Education Act.

MS. ABARAY: That's what I'm saying.

MR. ERNY: Right.

MS. ABARAY: But it doesn't have the whole rest of it, so it only has half sentences.

MR. ERNY: But the whole rest of it doesn't have anything to do with the Dietary Supplement Health and Education Act.

MS. ABARAY: Well, but Fred, what I'm saying is, it says, Section 402, as amended -- as amended by adding at the end, the following, and so you get a sentence fragment, so you have to read the rest of the sentence to get the whole thing, so do you have a copy of the whole statute? Would that be helpful?

MR. ERNY: Let me see.

BY MR. ERNY: (Resuming)

Q Before DSHEA was enacted in 1994, were there any federal regulations as they relate to current good manufacturing practices that related to dietary

supplements?

MS. ABARAY: I'm going to object to the extent you're calling for a legal conclusion, and especially because dietary supplements was not separated out as a separate entity before those acts, so to the extent you can answer --

A I don't know.

Q But in your report, you say that DSHEA provides this standard that you're measuring Metabolife against?

A Yes, and I believe that's really a quote that I took from a document that I couldn't find yesterday or the day before yesterday.

Q That document was the Dietary Supplement Health and Education Act?

A Yes.

Q And you're saying that this copy within your file that Ms. Abaray provided to you was not the complete copy of DSHEA?

A I don't believe it was, no.

MS. ABARAY: Just so the record is clear, the copy that we printed out are the DSHEA amendments to the Food, Drug, and Cosmetic Act, but unfortunately, you need the rest of the Act to put them in the proper context, and I don't have those here with me today.

MR. ERNY: I have, actually, only one copy of

21 U.S.C. 321. That's the statute that you were relying on to find this standard?

THE DEPONENT: It looks like it.

MR. ERNY: Can you point out for me where you find the language of the standard that you said you quoted?

MS. ABARAY: Can you give him the amendments back?

MR. ERNY: Yes.

THE DEPONENT: Can I have a minute?

MR. ERNY: Oh, absolutely. Do you mind if I come and look over your shoulder since I only have one copy there?

THE DEPONENT: No, sir. I'm not finding it, and this looks like at least part of what I had.

MS. ABARAY: Does this have the DSHEA amendments on it, Fred? The copy you gave him, does it have the DSHEA amendments included?

MR. ERNY: I pulled that from United States Code, and the second to the last page is the pocket part, so I assume that it does.

THE DEPONENT: Let me look a little more.

(Whereupon, the deponent reviewed documents.)

THE DEPONENT: This deals mainly with the

definitions, and I believe it was under Purpose.

MS. ABARAY: Is this --

THE DEPONENT: Let me see. That's part of

it. This isn't the exact quote, and I think that was an exact quote that I put in my report. Oh, let's see, first of all, it was amended by adding at the end the following, it is a dietary supplement and it has been prepared, packed or held under conditions that do not meet current good manufacturing practice regulations including regulations requiring, when necessary, expiration date labeling issued by the secretary under this subparagraph 2.

BY MR. ERNY: (Resuming)

Q So that's a reference in DSHEA to current good manufacturing practices, but it doesn't say anything in there about manufacturers being individually responsible for establishing their own manufacturing practices, correct?

A I didn't find it in here, no.

Q And in fact, the next section that you're looking at actually reserves to the Secretary of HHS, the ability to prescribe good manufacturing practices, don't they, or I should say, doesn't it?

A Yes, and they have -- they're similar along the line

in preparing those, I think.

Q So then your testimony would be, certainly, when you prepared this report in September, there weren't any current good manufacturing practices as they apply to

dietary supplements?

A I can't say yes to that, because there were some proposed regulations that were circulating for comment.

Q Had the Secretary of HHS promulgated binding current good manufacturing practices in September when you did your report?

A No, I don't think so.

Q So we're clear again, in the materials that you've just looked at, you don't see anywhere in there the quote that utilized to set the standard by which you're measuring Metabolife, which is, "manufacturers are individually responsible for establishing their own manufacturing practices to ensure purity and safety of their products."

MS. ABARAY: Let me just make a statement on the record. You've handed him 21 U.S.C. 321. The DSHEA amendments apply to 21 U.S.C. 342, 21 U.S.C. 331, and 21 U.S.C. 343, so he's only been given piecemeal copies of statutes.

MR. ERNY: And that's why I restrict it to what he's reviewed.

MS. ABARAY: Well, I just went through, let

records reflect, he did review all the statutes. He brought his notes in his file today, so I apologize for any inconvenience here. I mean, are you trying to get out are these minimum standards?

MR. ERNY: No, I'm trying to get out that he's setting a standard here that I don't find

anywhere in DSHEA, and he's using that standard to measure Metabolife by. That's the point.

MS. ABARAY: Well, do you think they don't have to have any -- they can just do whatever they want? They don't have to have any regs?

MR. ERNY: I'm not going to debate it with you on the record. He says that DSHEA provides this, and it's not in DSHEA. That's my point.

THE DEPONENT: I think it is, but I haven't found it.

MR. ERNY: Okay, fair enough.

BY MR. ERNY: (Resuming)

Q Now I'm going to change gears on you, Dr. Gerraughty.

A Okay.

Q When were you first contacted by Ms. Abaray's office about this case?

A I'm not sure. I don't remember.

Q Would it help to look at your file?

A It might. I think in September. It appears to be September.

Q Who was it that first contacted you?

A Ms. Abaray.

Q What were you told, if you can recall, in this initial conversation?

A I don't recall exactly, but I can tell you the

general gist was that she wanted me to review some materials in light of good manufacturing practices and what were required for dietary supplements.

Q Were you given an assignment or task, if you will?

A Yes, to report back on whether I felt that they were doing a good job with manufacturing practices.

Q Did you talk, during that conversation with Ms. Abaray, about current good manufacturing practices that were applicable to dietary supplements?

A Yes, she said that it was a dietary supplement that she was talking about, and that basically, she wanted me to look at it from that point of view, the fact that it was a dietary supplement.

Q At least as reflected in what will be Exhibit 3, in September you were sent a proposed rule from February 6, 1997 discussing the FDA's announcement that it was considering whether to institute rule making to even develop current good manufacturing practice regulations for

dietary supplements. Let me show that to you.

A Yes, I see it.

Q At least in September, you were aware that the Secretary of Health and Human Services had issued this advanced notice on proposed rule making where they were seeking comments to help it decide whether it should institute rule making to develop GMP's for dietary supplements?

A Or to modify them, yes.

Q And you say it were to modify them, so is it your opinion that there were current good manufacturing practices applicable to dietary supplements at that time?
A There were proposed rules from FDA.
Q Prior to receiving this information, were you, in fact, aware that HHS was considering whether to issue current good manufacturing practices applicable to dietary supplements?
A Yes, I was.
Q How did you learn about that?
A I attended a number of meetings during the year, symposiums, meetings, and I'm sure I learned it at one or more of those.
Q Did you provide any comments to Health and Human Services about their proposal?
A For dietary supplements?

Q Yes.
A Only what I provided from the floor. They had FDA people there at the meeting, and they had a discussion. They had workshops, and they had a discussion, and I provided some there, but I didn't write them.
Q Where was this meeting held?
A I don't remember. I think it was New Orleans.
Q When was that?
A Early last year I would guess. And I talked to FDA people on the phone, because I still do consulting for

them.
Q Was it your testimony that you were asked about GMP's for dietary supplements?
A No. I was attending their meeting, and they were talking about it, and they asked if there were any questions or comments, and I made some comments and asked a couple of questions.
Q Do you remember what comments you made?
A I remember one that I made -- that I thought they needed to make the regulations a little tighter than they were then, because a number of these dietary supplements now contain drugs.
Q Are what you're saying, at least as of last year, is that you believed when you were at this meeting in New Orleans that there were current good manufacturing

practices applicable to dietary supplements?
A Yes.
Q And you felt that the existing, at that time, current good manufacturing practices were not tight enough?
MS. ABARAY: He was referring to the proposed regulations, Fred.
MR. ERNY: You were referring to the proposed regulations or the actual regulations?
THE DEPONENT: The proposed regulations.
Q Do you know how it was that Ms. Abaray came to contact you or find out about you?
A I had testified in a case in Cheyenne, Wyoming in

which she was involved some years ago. That's where I met her.
Q That would have been the albuterol cases?
A Yes.
Q For Copley?
A Yes.
Q And you testified there about good manufacturing practices for pharmaceutical products?
A Yes.
Q When you were first contacted by Ms. Abaray I presume that you were provided certain materials to review?
A Yes, I was.
Q And at least your report, which has been marked as

Exhibit 4, suggests that you reviewed the deposition of David Brown and the deposition of Dirk Aschmoneit and the deposition of Michael Scott?
A Yes.
Q When you were first provided materials, were you provided anything other than those three depositions?
A I don't recall whether there were other things or not.
Q Since that time, you've indicated to me that you've reviewed Jeff Brady's deposition?
A Yes.
Q And the exhibits to that?
A Yes.

Q And you were also provided another packet of information about the Canadian regulatory action and some other things, and you're going to provide that list to me, right?
A Yes, and also the Brown deposition I got later.
Q The David Brown deposition you got later?
A Yes.
MS. ABARAY: That might have been Boozer.
THE DEPONENT: Then Boozer was later.
Q Did Dr. Boozer's deposition have anything to do with good manufacturing practices?
A A little in that it was a study, and it wasn't well

controlled, but it wasn't a key document as far as I was concerned.
Q It impacts on any opinions you may have with regard to the Boozer study, but it doesn't impact on current good manufacturing practices, is that accurate?
A I think that's reasonably accurate, yes.
MR. ERNY: Ms. Abaray has pointed out something in DSHEA and underlined it for you. Tell me what it says?
THE DEPONENT: "fails to meet the quality (including tablet or capsule disintegration), purity, or compositional specifications, based on validated assay or other appropriate methods, that the supplement is represented to meet".
Q You testified earlier that the standard that you've

set forth in your report you believed was a quote that you pulled from some of the materials, and what you've read here, doesn't match up with that quote, is that right?
A No, it doesn't match up with that quote, and I still believe that was an exact quote.
Q So that exact quote, at least as far as the materials that you've reviewed, isn't in DSHEA?
A I don't know whether it is or not.
MS. ABARAY: It doesn't have quotation marks on it in the report, either.

Q After you reviewed the materials, you prepared this preliminary report, correct?
A That's correct.
Q Did anybody assist you in preparing it?
A Yes, my daughter typed it.
Q Did you receive any input from Ms. Abaray or anybody on her staff?
A About the report?
Q Right.
A Only after I sent it.
Q So you created a draft and sent it to Ms. Abaray?
A Yes.
Q I'm going to hand you a document which I pulled out of your file. Is this the draft that was circulated to Ms. Abaray?
A I'm not sure anymore.

Q I say that because I note that there are some penciled in corrections on there, which suggests that it was a draft.
A I think it is. I think it's the one that I faxed to her.
Q So you sent a draft to her, and what happened next?
A She called me, and we talked. She said she thought the report was okay. She didn't have any problems with it. She asked me a couple questions about it, terms that I used

that she didn't understand, but I notice that this is the draft, I'm sure, because I made some mistakes in English and spelling and so forth, and I corrected these primarily so that my daughter could do a revised.
Q Would you mind if we write on that document the word draft, just so that it's clear when we get the copies back from the court reporter?
A I don't have any problem.
Q Can I give you a pen and ask you to write that on there?
A Sure. Okay.
Q Thank you, and I'll put that back in your file. Then, after you made the revisions to this draft, the next report was the final report that you signed and prepared and what's marked as --
A Yes, the other one that you have.
Q Which is Exhibit 4?
A Yes.

Q Other than Ms. Abaray and your daughter who was typing it, have you discussed the report with anybody else?
A I don't believe so.
Q You haven't talked to anybody at FDA or anybody like that?
A Well, I talk to people at FDA all the time, and I might have talked about some general issues, but I didn't

talk about the specific report.
Q What general issues would you have talked to them about?
A They frequently call and ask my opinion on things, but it's usually them calling me, not me calling them.
Q Did you discuss Metabolife with any of the FDA folks?
A No, not as such. I might have discussed some of the things regarding Metabolife, one or two, but I didn't identify it.
Q What do you remember discussing with the folks at FDA about Metabolife?
A They were indirectly related to the Metabolife report. I don't remember anything, to be honest with you, that I did.
Q Did you memorialize any of those discussion with the FDA folks? Are there any notes about that?
A No, they were pretty brief.
Q Did you meet with Ms. Abaray to prepare for the

deposition?

A No, she came in last night, and we had dinner together, is all, my wife and I and Ms. Abaray.

Q Had your wife met Ms. Abaray previously?

A No, but she talked to her on the phone.

Q Did you have a good meal?

A Yes, pretty good.

Q I'm sure it was better than the one that I had. When you had dinner last night, did you discuss the deposition?

A We discussed that I was going to come here this morning and the time and things like that, but no, not really in any detail.

Q Did she give you the copy of DSHEA last night or was that provided to you this morning?

A No, this morning.

Q Any other documents that were shared?

A No. She looked at my file, I think, but that's all.

Q Did she pull anything out of the file?

A No.

Q We talked previously about recently the FDA proposing a rule to establish current good manufacturing practices for dietary supplements. Do you recall discussing that?

A Yes.

Q And that happened on March 13th?

MS. ABARAY: What year?

MR. ERNY: Of 2003.
A I don't remember.
Q Have you read anything from the Federal Register where the FDA recently --

A Yes, I have, but I don't remember the details. Yes, I have, but I didn't remember what the date was on it.
Q How did you hear of that?
A Through friends who also do consulting.
Q And you actually reviewed the document?
A I don't think I did.
Q So you wouldn't be relying on that for your opinions in this case?
A No.
Q In Exhibit 4, your report, is that a complete statement of your opinions in this case?
A No, it says, preliminary.
Q What other opinions do you have that aren't reflected in that case?
MS. ABARAY: Let me just also add, before you get started, these reports were filed in October, I believe, and we've taken several depositions since then which have been provided to him.
MR. ERNY: I understand. That's why I'm asking him.
THE DEPONENT: And I've got notes in that folder on some of those that I did since this.

MR. ERNY: Do you need to look at those notes to tell me what your opinions are?

THE DEPONENT: Yes, I would need to.

MR. ERNY: Let me give you your notes, then. Just so you know where we're going, you have a preliminary report that sets forth certain opinions, and I'm here today to make sure that I get all the opinions that you have, so that we can talk about them.

THE DEPONENT: Okay. I may need to compare it to 4, too.

MS. ABARAY: I'm putting all those back together.

A I got a lot of information from the deposition of Jeff Brady, which had been taken on February 20, 2003, and I, according to my notes, reviewed it on the 19th of March. It confirmed an opinion that I had earlier that ACERIS audits were not on a regular basis. Although they mentioned that they would be yearly, there were gaps. I learned that Dr. Dash, during the ACERIS inspection, took no notes during audits, or at least Jeff Brady said he took no notes, and he gave no written documents to Alpine about the audit.

MS. ABARAY: Let me just stop you there. I think he has opinions about that, Fred? Do you want to --

MR. ERNY: We'll go through that.

THE DEPONENT: Shall I continue?

MR. ERNY: Yes.

A Sometimes my handwriting is difficult to read. I've got problems with my eyes. He disagrees with the observations on the hand-washing facilities, and I couldn't tell whether they had those extra ones he talked about or not, but he didn't seem to think that hand-washing before going back to the manufacturing area was that important, but I do. He believes that log books are not critical because everyone makes errors. He stated that Metabolife does not review logs for accuracy and completeness. I consider that to be a very poor practice, not to review them. He keeps copping out that everyone makes errors. Had a sign that Alpine was a registered drug establishment. It was not. He said he was unaware of the sign. He didn't review previous 483's, but he argued that there were not repeat problems. He'd have to review the previous ones to see that there weren't. He admits failure to follow aerobic count limits. The aerobic counts were high. He admits the failure to follow those but kind of shrugs it off. There was a storage problem, segregation, storing a contaminated product with ephedrine. He also stated there were no written rework SOP's, standard operating procedures for reworks. There were six lots of a product formulated with a rejected raw material. One of the very serious things is when he talks

about equipment or an area being clean. As you read his deposition, he means visually clean. There's a difference between clean and visually clean. In other words, he feels if you can't see anything on it, it's clean, and he's their chief quality assurance person. There were furniture and unnecessary equipment, file cabinets and things like that, in a manufacturing area that were very dirty and dusty, and that's a serious problem with safety. You can have cross-contamination. They had no evidence of validation of the use of ethylene oxide to reduce the bioburden or the aerobic counts that were high or its potential effect on other components in the Product 356. It also established, in more detail for me, that the amount of ephedrine was being -- that this would involve daily, that exceeded that allowed by Texas and Ohio laws. Innovative Health Products, which is one of their contract manufacturers, had an incomplete quarantine on the computer only. That's not enough. You've got to label the containers so there can be no mix-up. Chemins was never audited by ACERIS is a note that I have, and they were later. I found one later, later on after I reviewed this deposition. It appears that the assay for ephedra alkaloids was not validated, proven to work. Brady questions the accuracy of the method used to assay for ephedra and caffeine. That's HPLC, which is highly

accurate. While specs can be changed, this has to be done by a proper control system. He also says that caffeine is a GRAS substance, generally regarded as safe ingredient. It's not. It's an active compound, and typically, GRAS substances are fillers like those things of that nature. They adjust the potency up or down in a rework. They make a batch of the product, and then they check it, and if they get an out of specification result, they retest it, but they don't test the same sample, and it's typical that you would retest the same sample. Then, if the second sample passes, they release it. If it doesn't, they rework it. This is at the finished product stage with the tablets. They take the tablets and grind them up and spike it if it's low, or dilute it if it's high, to adjust the potency of ephedrine/caffeine at least. That's an extremely dangerous practice, and would certainly affect safety of the product. I think that the attempt to rework finished tablets is unacceptable and dangerous. It increases the chances for cross-contamination, it could dilute down some ingredients and not others. It's an extremely bad practice. That involved safety. That's it on his. This is the packet of materials that kind of are miscellaneous. It had Bates numbers on the cover sheet. The Bates numbers were MET 50982 to MET 51182. It's a series of letters and copies of certifications regarding

ACERIS certification of -- this is where I found the -- is it Chemins?

MS. ABARAY: Chemins, I think.

A That's where I found the Chemins one, although Jeff didn't think they'd ever had it done. Alpine Health Products and Innovative Health Products appear to have gaps. It covered the periods between 1997 and 2002. Scott, in his earlier deposition, had said that they do that annually. There weren't annual ones in there. There were several missing. It also contained the Form 483 issued on 1/21/00 and the EIR for an inspection of 1/13/00 to 1/21/00. These are both FDA documents listing six objectionable conditions, including poor training, poor raw material control, inadequate sanitary conditions, uncleaned equipment, and inadequate pest control in the warehouse. The EIR also discussed inadequate labeling controls. It said that photos were taken, but there were no copies in the materials that I got. Let's see. I have to read my own writing again. There was a follow-up report on May 16, which showed a number of GMP deficiencies. Many remained uncorrected in a follow-up inspection.

Q What facility was that?

A I believe it's Innovative Health Products.

Q The portion that you're referring to are Jeff

Brady's audits of Innovative Health Products?
A Yes, and he had two follow-ups that were both in there, and they found several that still hadn't been done, and they found some new ones.
Q Do you find that Jeff Brady conducted thorough audits of Innovative Health Products?
A I beg your pardon?
Q Did Jeff Brady conduct thorough audits of Innovative Health Products.
A I'm not sure, because he doesn't list some areas that would normally be listed. And then, there's a series of follow-up letters by Brady to Innovative Health Products, sent by Brady on 5/23/01 and 11/12/01. On 2/12/02, there were still repeat issues, six of them. There were also some new and different problems cited. There is a memo of a follow-up visit. There's a long series of what I think are room temperature stability results for the various ingredients that are in Product 356. There's some accelerated and room temperature stability. At least that's what it appears to be. It's not well labeled. It's not well identified, so it's kind of impossible to get too much out of it. There's no indication of what the method was that was used or whether it was stability indicating. Do you want me to explain what I mean by stability indicating?

Q Sure.

A Some assays, some tests, show only whether the material, let's say, ephedrine, pick ephedrine as one, and nothing else. I mean, that method only picks up the active that you're trying to test for. If there are some derivatives or degradation products that get into the batch, it would not indicate those. That's stability indicating. You only want to know what the stability is of the drug.

Q Are there current good manufacturing practices applicable to dietary supplements that require stability testing?

A I think that safety requires stability testing. Otherwise, you're not going to know when they expire.

Q So the answer would be?

A And it could involve purity issues, too.

Q But my question was, are there any current good manufacturing practice regulations applicable to dietary supplements that require stability testing?

MS. ABARAY: I think this has been asked and answered.

A Yes, in my opinion, there are. Oh, and then I found out from those documents, too, there's no indication of the permissible range for chromium. There's a long list of companies, 19 of them, that are suppliers of ephedra to the

contract manufacturers and to Metabolife. That's way too many to assure proper control. Typically, firms, even in the food industry, will have two or maybe three suppliers.

I've seen it up to four, but I've never seen anybody have 19 suppliers that they're trying to control. There was some other internal audit information, but it wasn't labeled, so I can't identify what it would go to.

Q Those points are reflected on the notes that you created when you read Jeff Brady's deposition, looked at the exhibits to Jeff Brady's deposition, and then these additional documents that you received?

A Right. That's all of the yellow pages. I think that's all the notes that I had.

Q So in connection with your report and what you just told us, that would constitute your opinions in this case?

A I'm sorry, that would what?

Q That would constitute what your opinions are in this case?

A Yes, and I don't think I had a separate one for Mr. Brown, but he verified some of the things that the other had.

Q Let's talk about a little of these things.

MS. ABARAY: I tell you what. If you're getting ready to switch, maybe we could take a little break?

MR. ERNY: Sure, that would be fine.

(Whereupon, there was a brief recess.)

MR. ERNY: Before we go on -- Christina, here on the phone, asked that we try to speak up a little

bit. I guess it doesn't come through clearly.

THE DEPONENT: Okay, sorry.

MR. ERNY: Can I see your file, there, Dr. Gerraughty?

THE DEPONENT: Sure.

BY MR. ERNY: (Resuming)

Q Dr. Gerraughty, when you read Jeff Brady's deposition and created these notes of the deposition, and you created these -- you read to me the opinions that you've had. I want to talk to you about some of those things. You referenced a FDA 483 inspection report from January, 2000, correct?

A Yes.

Q Do you know whether Alpine was, in fact, manufacturing Metabolife 356 in January of 2000?

A I don't know for certain. I wasn't there.

Q Did you pull anything from Jeff Brady's deposition that would indicate whether they were manufacturing Metabolife 356 at that point?

A I don't recall.

Q A number of the criticisms in the 483 report dealt

with the cleaning of mixing vats for liquid product. Do you recall that?

A Not only mixing vats, other pieces of equipment, too.

Q For liquid products and things of that nature?

A No, some of them were -- they used a Fitz mill.

It's called a Fitz mill. It's a Fitzpatrick mill. When they ground up these tablets when they were too potent or less potent than they should be, they ground them up in a Fitz mill, apparently, from what they said, and a Fitz mill is -- you could look at it and say, hey, yeah, it's clean. It looks visually clean, but down inside in the cutting chamber that actually cuts these up, there could be all kinds of powder.

Q I want to restrict my questions, though, to the FDA 483 report that you're relying on, and in particular, that portion of it which talked about the mixing vats for the liquid product. Do you remember that?

A Yes.

Q Metabolife 356 is not a liquid product, is it?

A No.

Q And the 483, Establishment Inspection Report, didn't make any comments about mixing vats for powdered substances, did they?

A As I recall, no.

Q You also talked about, there was no evidence of validation of ethylene oxide use in the product. Do you remember that?

A Yes.

Q Are you aware of whether that product that was treated with ethylene oxide was actually shipped?

A No, I'm not.

Q You mentioned that the ACERIS audits are not on a regular, yearly basis?
A Scott said that they were, but I didn't find that to be true, and what Jeff Brady said is, he didn't think they were on a regular, yearly basis, either.
Q Do you find the fact that it wasn't audited on a yearly basis to be a problem?
A No, not particularly, except that that was the only audit that they recommended, or that they carried out with their contract manufacturers. FDA is only required to inspect every two years, but there was more than two years between some of the ACERIS qualifications.
Q When you say the FDA is required to inspect every two years, what is it that they're required to inspect?
A The pharmaceutical plants.
Q And of course, Metabolife 356 is a dietary supplement, right?
A Well, it contains a drug.

Q Why is it that you say it contains a drug.
A Ephedrine is a drug, and ephedra alkaloids are drugs. In my opinion, it's a drug.
Q But the FDA doesn't treat Metabolife 356 as a drug, does it?
A It doesn't specifically state it, as far as I know.
Q It treats it as a dietary supplement, right?
A Yes, right.
Q And in the regulatory scheme of things, dietary

supplements are not drugs, correct?
A No, they're closer to foods.
Q And so your opinion that these are drugs is actually quite different than the FDA's?
A I don't know that it would be different than the FDA's, but the regulations don't spell it out.
Q The regulations don't spell out that it's a drug?
A Well, they don't specifically deal with ephedra, as such, or caffeine.
Q Now, you also talked about the discussion of the log books in Jeff Brady's deposition, remember?
A Yes.
Q And again, those log books that they were talking about in that Establishment Inspection Report dealt with the cleaning of the liquid mixing vats, correct?
A That's right.

Q And you're not aware of there being any errors or irregularities in log books, as it relates to the mixing of the powdered substances to create Metabolife 356?
A Yes, I am. They say they don't review log books. How would they know?
Q Have you reviewed the log books?
A No, I've reviewed what they said about them.
Q So you're not aware that there's any errors in them?
A I'm not aware what?
Q That there are any errors in them?

A No, other than the ones that were cited specifically.
Q Relating to the liquid product?
A That bothers me a little bit. I think there was one related to the solid product, too. I think there was a reference to that, to one of the pieces of equipment. There certainly was a reference to the Fitz mill, and you would not use a Fitz mill for liquids.
Q And you're referring to, now, the use of the Fitz mill in the FDA Establishment Inspection Report?
A No, there was something in the Brady deposition about it, too.
Q And this was Jeff Brady's inspection of Innovative Health Products, right?
A Yes, that's correct.

Q Was Innovative Health Products actually making, at that time, Metabolife 356 for public consumption?
A I don't know.
Q You also mentioned the Ohio and Texas regulations for ephedra containing products?
A Yes.
Q And your thought that the test results of the specs would exceed the Texas and Ohio limits?
A I got that from the deposition, yes.
Q Do you know what the Ohio limits are?
A I can't recall offhand, but I looked at them at the time in the deposition.

Q I'll represent to you that the Ohio limits call for the ingestion of not more than 100 milligrams of ephedra alkaloids in any 24-hour period. Now, the results that you saw in the specs, they demonstrated ephedra alkaloid amounts in the 13's, correct, 13 milligrams?
A Yes, some of them were.
Q And the Metabolife specs had an upper limit of 12.84 milligrams?
A That's correct.
Q Do you know how many Metabolife 356 tablets Robin White took in any one day?
A I have no idea.
Q I want you to assume that the most she took in any

one day was six tablets, okay?
A Yes.
Q Let's just assume that we had a 15 milligram reading in some of these results. Can you assume that for me?
A Can I what?
Q Can you assume that the results of these tests showed that there were 15 milligrams in some of the tablets?
A I can't assume it, no.
Q Well, what do you recall being the highest value of the spec, for caffeine -- I'm sorry, for ephedra?
A I can't recall, offhand, without looking.
Q Let me ask you to assume that it's 15 milligrams?

A Okay.
Q If it's 15 milligrams per tablet, and Robin White took six tablets per day, that would mean that she's taking 90 milligrams of ephedra alkaloids per day, correct?
A If the assay is correct and so forth, and the number of pills she's taking is correct, yes. Six times fifteen is ninety.
Q Right, so at least as far as Robin White is concerned, she would not be exceeding the Ohio limits?
A I don't know. I don't know that she took six tablets a day.
Q Well, I want you to assume that she took six tablets

a day.
A Assuming that, it could be 90 milligrams, and it would be below the Ohio standard.
Q Thank you. Now, you also said, assuming the assay is correct. You have some question that maybe it's difficult to say, and it may not be correct?
A Yes. For example, when they got high results or low results from their own spec -- they set the specs themselves. When they got high or low results, according to Aschmoneit, what they did was, they merely ran another assay, and if the second one came out okay, they released it. They didn't use the same sample that the original test was done from. Usually, you save some of the sample and retest it. It was a different sample that they pulled, and then, they retested it, and if it passed, it was okay, I

mean, they released. That's what Aschmoneit says, if it was okay. If it wasn't, they reworked. They took the finished tablets, ground them up, and reworked and spiked them or diluted them, depending on what the result was.
Q Is it your testimony, then, that when a second test was done, and it was still out of spec, that product always got reworked?
A No, it's not my assumption, but it shouldn't get reworked at all, because it's a one out of two chance which one was right -- the first one or the second one.

Q We'll talk about reworking, but didn't Mr. Aschmoneit also testify that if it didn't make specs again on the second test, that it was sent back to the manufacturer and it wasn't sold?
A Yes, but he also mentioned that some of it was reworked. I don't know if every lot was.
Q You also said that the assay for the ephedra alkaloids was not proven to work. Do you remember saying that?
A No, I don't think that's what I said.
Q In fact, the assay that they used was the HPLC assay, high performance liquid chromatography?
A I said I saw no data to support that it was done properly. As accurate as HPLC is, if you don't prepare the sample properly, you don't get reliable results.
Q Did you see any data about preparing accurate

samples?
A About preparing what?
Q Accurate samples?
MS. ABARAY: Preparing samples accurately.
MR. ERNY: Yes, preparing samples accurately?
A I saw something about that, but basically, what I saw was Aschmoneit saying that they tested so many samples and then if they didn't make the spec, they retested, and at one point, he indicated he didn't know whether it was

the same sample or not. At another point, he said it was a different sample.
Q Did Mr. Brady talk about samples that were pulled and tested?
A He may have. I don't know, but I didn't rely on what he said.
Q You didn't rely on what Mr. Brady said?
A I don't think there was anything about sampling.
Q You talk about relying on Mr. Aschmoneit. You understand he's a product manager?
A I'm sorry.
Q You understand that Mr. Aschmoneit is a product manager?
A Yes.
Q What do you understand a product manager does?
A Well, I can only describe what he said he did.
Q Okay.
A I mean, a product manager can do a lot of different

things. Basically, he was responsible for the product.
Q In effect, he described it as a marketing position, didn't he?
MS. ABARAY: I want to enter an objection here. You, Metabolife, offered Dirk Aschmoneit as the knowledgeable 30(b)(6) witness to testify about manufacturing, so if you want to turn around now and

say he doesn't know anything about manufacturing, which I won't argue too much if he doesn't know anything about manufacturing, but I don't think anybody in your company does. But I just want the record to reflect you set him out in your Rule 26 disclosures as the manufacturing witness.
BY MR. ERNY: (Resuming)
Q In fact, Mr. Aschmoneit described product manager as a marketing position, didn't he?
A No, I don't believe so.
Q Have you read anything about, other than Mr. Brady, have you ready anything about the personnel used at Metabolife's contract manufacturers?
A Let me think that one over. By name, you mean?
Q Or generally about them?
A Well, I think, I learned some things generally about them, because they were manufacturing the product, and they'd say, the labeling supervisor or the production manager or the worker on the line, whatever the case may

be, but I didn't see an awful lot about them.
Q What is the United States Pharmacopoeia?
A It's an official reference book of the U.S. government on drugs.
Q Does it have guidelines for manufacturing practices for nutritional supplements?

A I don't know. I can't recall whether it's in there or not.
Q Are you aware, at the FDA's request, the American Herbal Products Association proposed good manufacturing practices for dietary supplements?
A I read something about it, but I didn't have much detail on it.
Q Do you know who wrote them for the American Herbal Products Association?
A I think it was said that somebody from Metabolife did.
Q Do you know what the National Nutritional Foods Association is?
A No.
Q Do you know if it has any guidelines for good manufacturing practices for dietary supplements?
A If they do, I don't recall.
Q Well, did you review them?
A I don't recall whether I did or not.
Q You talked in your report about specification problems, and in particular, that Mr. Aschmoneit had no

knowledge as to how they were decided upon or what rationale was used. Do you remember that?
A Yes, I do.
Q Why is it important knowing the source or the

rationale for the specifications?
A Because the specifications shouldn't be changed by anybody who's not a person in high authority, a person well up in the company. It was not only mentioned in Aschmoneit's deposition. It was also mentioned in Brady's and in Brown's.
Q Going to the time that the specifications were set, when they were originally decided and set up, why is it important to know the background as to how they were originally set up?
A If you have a problem with them later on, you want to know who to go to, who's responsible for them, in my opinion. Basically, they were allowed to set their own specs. They could set their own specs, and if somebody came in and said, hey, this spec is not good, or if something changed, they found out more in toxicity of one of the ingredients and so forth, you want to know who had the ability to change specs, because you might want to reduce it, or you might want to increase it.
Q And in fact, the specs that were originally set up were actually, as they progressed over time, made tighter, weren't they?

A Some were.
Q Can you testify to any that were made looser?
A There was one that wasn't tightened.

Q So if they were changed, they were made tighter?
A The specs were, yes.
Q You also say that the quantitative requirements were very loose. What do you mean by quantitative requirements?
A Well, there were several reports of assays of the material, and although the specs weren't extremely tight, for example, caffeine, you could go 10 percent below or 25 percent above. That's a pretty big range for caffeine, which is an active compound. Basically, the specs were too loose in some categories.
Q Too loose as compared to what?
A As compared to what you would normally find.
Q Normally find where?
A In the vitamins, minerals.
Q And the drug pharmaceutical field?
A Yes, and the pharmaceutical field. Normally, you wouldn't allow a 35 percent swing in caffeine in the pharmaceutical world.
Q And of course, again, we're not in the pharmaceutical world, though, are we?
MS. ABARAY: Well, you asked him about the pharmaceutical world.
THE DEPONENT: Yes.

BY MR. ERNY: (Resuming)

Q Have you compared the specs and the swing, as you call it, to what's used by other dietary supplement manufacturers?

A I didn't use their product, the label as such, but I saw some in the USP as to what the minimum daily requirements were, and what was toxic and what wasn't, yes.

Q But have you seen any specs for high values and low values?

A No, they typically don't show specs. They show minimum daily requirements.

Q And there's no minimum daily requirement for caffeine?

A No.

Q And there's no minimum daily requirements for ephedra alkaloids?

A I hope not.

Q You would agree that plant derived dietary ingredients are characterized by greater variation in product quality than synthetically derived dietary ingredients?

A I wouldn't characterize it as part of the quality. I would say potency. Yes, there would be differences in potency.

Q Well, if the FDA made that statement, would you disagree with it?

A That there were differences in quality?
Q Greater variation of product quality?
A No, basically, I wouldn't, although they're plant materials and they're very variable. They're more variable than synthetics.
Q Right.
A I wouldn't characterize it that way. The key issue is potency.
Q Your report also makes reference to at least the possibility of pharmaceutical grades of ephedrine being used and there not being an indication on the label, do you remember that?
A Yes, I do.
Q Do you have any evidence that a pharmaceutical grade ephedrine was used in Metabolife 356?
A Only that they talked about spiking, and they talked about dilution, because the ephedrine being higher. I think it was more likely it wasn't ephedrine, because, typically, the results were over 12.84.
Q I didn't hear. Did you say it was more likely that there wasn't ephedrine?
A It would be less likely that ephedrine would be spiked or diluted than caffeine.
Q Other than the reference to the words "spiking" and "dilution" in these depositions, do you have any evidence

that pharmaceutical grade ephedrine was used for Metabolife 356?

MS. ABARAY: I'm sorry, you're saying other than the depositions?

MR. ERNY: His question was there were references to spiking and dilution, and I'm asking him, other than those -- if that's what he bases his opinion on, that there was pharmaceutical grade ephedrine in it, that's fine. I'm just trying to find that out.

MS. ABARAY: I don't think I -- maybe, could you rephrase your question?

BY MR. ERNY: (Resuming)

Q Let me ask you this, do you have an opinion as to whether pharmaceutical grade ephedrine was used in the manufacture of Metabolife 356?

A I don't know.

Q You also talked in your report about caffeine. You said, when you're talking about labeling problems, "The principle problem in this area was that synthetic materials used were not indicated on the labeling, particularly for caffeine." What did the label say?

A The label said Guarana, Guarana seed, as I recall.

Q Did you see any labels that also listed caffeine under other ingredients?

A I did not.
Q In your opinion, what should the label have said?
A It should have indicated what the content was in terms of if they used Guarana seed, how much did they use of that. If they used caffeine to spike it, to increase it, that should be on there, too.
Q In what way? What would you suggest the labeling should say?
A The milligrams, the percent, or some quantitation of the amount of Guarana seed and some of the caffeine USP.
Q Can you point out to me one dietary supplement product that uses such a label like that?
A That what?
Q That uses such a label like that?
A I can't specifically point one out, but I have seen some where they will use a mixture of two alkaloids and other derivatives, or something of that nature, but they list it on the label. I've seen instances in which there are two sources for one drug, one a natural source and one a synthetic source, and they list both.
Q Do they list it as a synthetic caffeine?
A No, I don't think they say synthetic. I think they say caffeine USP, anhydrous caffeine USP.
Q Do you recall any label that contains caffeine anhydrous USP?

MS. ABARAY: For what product? Are you talking --

MR. ERNY: Any product.

A Specifically?

Q Yes.

A Yes, Metabolife 356.

Q Is it your opinion that the Metabolife label says caffeine USP anhydrous on it?

A No, it doesn't say that.

Q And I'm asking, can you tell me any label that does?

A Not offhand. I'd have to do some research on it.

Q When did you detect this use of USP caffeine first occurring?

A I don't recall the date. It was in one of the depositions. It was in two of the depositions.

Q Correct me if I'm wrong, but my recollection is that these documents arose in 1999?

A I think that's correct.

Q Do you know when Robin White first started taking Metabolife 356?

A No, I don't know.

Q Do you know when Robin White stopped taking Metabolife 356?

A No, I don't.

Q So you don't have any idea as to whether Robin

White's Metabolife 356 contained USP caffeine?

A I don't know.
Q How would we know if it did?
A If somebody had checked it beforehand.
Q Do you know if Robin White retained the Metabolife 356 that she took?
A Do I know if she what?
Q If she retained it, if she kept it?
A I don't know what you mean by "kept it."
Q Well, you said if we could check it out, we could find the product that she used and we could test it, couldn't we?
A Yes, you could.
Q Do you know whether Robin White kept the product so that it could be tested?
A No, I have no idea.
Q I'll represent to you that her mother, Ocie Perry, testified that she threw the product away. Because of that, nobody can test it, can they?
A If it's been thrown away, no, unless they have reserve samples.
Q And if she threw the bottle away, we wouldn't even be able to get a lot number or anything, would we?
A Probably not, but some pharmacies keep lot numbers in their record keeping systems.

Q And you're talking about for pharmaceutical products?
A Basically, yes.

Q You wouldn't expect a pharmacy to keep lot numbers for Metabolife 356, would you?
A No.
Q Is caffeine an approved food additive?
A What do you mean by "an approved food additive?"
Q Well, can caffeine be used in foods?
A Oh, yes.
Q And you testified that caffeine is not on the FDA's generally recognized as safe list?
A Yes, I don't believe it is.
Q Did you actually go through the regulations to see if, in fact, it was?
A I went through the copy that I had at home. It wasn't the most recent copy. Then my wife ran it through the computer, ran the GRAS list through the computer. It wasn't on the GRAS list. It was on the computer, which was recent.
Q So is it your opinion that caffeine is not on the FDA's generally recognized as safe list?
A I don't believe it is.
Q Is the molecular structure of synthetic caffeine different from a natural caffeine?

A Sure.
Q In what way?
A Well, you've got other things in the Guarana seed. You've got other materials in there besides caffeine.

Q I'm specifically referring to the actual caffeine molecule or atom, if it's appropriately called that way.
A It should be the same structurally.
Q Are there any pharmacological differences?
A Oh, there could be, because there's other materials in --
Q Are you aware of there being any pharmacological differences?
MS. ABARAY: I don't think you let him finish his answer.
MR. ERNY: I'm sorry.
A I don't know.
Q Are there any pharmacokinetic differences?
A There could be, I don't know.
MS. ABARAY: I think your question if vague. Differences between what? Let's be a little more specific.
Q Have you reviewed the literature to see if there are any pharmacokinetic differences between herbal caffeine and synthetic caffeine?
A No.

Q Is one more dangerous than the other?
A I don't know. I don't know what the other materials are that are in that.
Q Do you know whether caffeine is an approved over-the-counter stimulant?
A No, I can't recall. I know it's in Coke, tea and

coffee.
Q Let me ask you a question. Are you going to be rendering an opinion as to whether Metabolife 356 is safe and effective in this case?
A No, I'm going to be rendering an opinion as to whether I think they followed the practices that they should have regarding safety and purity.
Q Are you going to offer any opinions as to whether Metabolife 356 played a causal role in Robin White's injuries, or in any of these plaintiffs' injuries?
A No.
Q Your report also notes -- it refers to some what you characterize as poor documentation, and you said you found large gaps in documents which made them inadequate to ensure quality control or qualify assurance?
A Yes.
Q Does this, then, mean that the finished product was impure?
A No, but it could be.

Q We just don't know, though?
A Well, you can't be certain unless you check it out.
Q Does it mean that the finished product was unsafe?
A It certainly could.
Q But again, we don't know?
A I'm not sure you could know.
Q You also talked about -- in the context of labeling

problems, you made the statement that wordings were eliminated or changed without adequate explanation, and as an example, you gave a toll-free number to report adverse reactions was eliminated during one label change, remember that?

A Yes, I do.

Q Did you review the labels of Metabolife 356?

A The ones that were in the depositions. They had -- there were some exhibits of labels.

Q Did those labels provide an 800 number on them?

A I can't recall whether they all did or not.

Q Some of them did?

A I think I saw an 800 number on one.

Q Did any of those labels say anything about these numbers to report adverse reactions?

A I don't think they spelled it out, no.

Q So is it your opinion that that number was placed on there for people to report adverse reactions?

A I don't know.

Q So then, the statement in your report that there was a toll-free number to report adverse reactions which was eliminated during one label change, really has no support, does it?

MS. ABARAY: Do you want to refer to where you're looking at in the report?

MR. ERNY: The top of page 6.

A Well, I maybe went too far with my interpretation

on that, in that I believed that the reason for the toll-free number was if there were any problems with the product. Yes, I did. I don't know why else you'd put a toll-free number on there.

Q Well, in fact, the label says for health questions, call, and then it list the 1-800 number, doesn't it?

A I can't remember.

Q Have you ever been asked to consult with the FDA as part of the approval process on whether labeling for a particular drug is adequate?

A Yes, a few times in the past, yes.

Q For how long had that consulting been going on?

A I've been consulting with FDA since approximately 1958.

Q My question, though, relates to for how long have you been consulting with the FDA?

A For how long?

Q As part of the approval process on whether labeling for a particular drug is adequate?

A Since probably 1958, from time to time. I don't do it every day.

Q Dr. Gerraughty, do you remember being deposed in 1992 in the Susan Sidel case?

A Yes. I don't remember the details, but I remember.

Q Well, and I only have one copy of this, so let me come over, and you can read along with me.

A Okay.
Q First of all, this is a copy of that deposition.
A Okay.
Q You were asked, beginning at page 61, have you ever been asked to consult to the FDA as part of the approval process on whether a labeling for a particular drug is adequate, and your answer was no. First of all, did I read that correctly?
A Yes, you did.
Q Was that your testimony, then?
A I don't recall, but if it was, I had been.
Q So then, your testimony was wrong, then, before?
A Yes, it was wrong, not intentionally.
Q Are you going to render any opinions as to the labeling of Metabolife 356 in this case?

A Only in the sense that the label control wasn't good, in that they had two different versions of the same label in the label issuing room, and there could be a potential for mix-up.
Q And that relates to the FDA establishment inspection report. That was one of the criticisms that the FDA brought up?
A I can't recall whether it was or not, but it could have been.
MS. ABARAY: I just want the record to reflect he also has a heading called labeling problems in his written report.

MR. ERNY: Well, that's why I'm asking him, because he said he may have gone too far on this toll-free number to report adverse reactions.

MS. ABARAY: I think he restated his testimony.

MR. ERNY: The record will be clear.

MS. ABARAY: I want the record to be clear that he put comments regarding labeling problems in his written report, and we've already covered some of those earlier. You asked about the synthetic products.

BY MR. ERNY: (Resuming)

Q Now, your report also talks, again on page 6, about

excessive out of specification results?

A Yes.

Q Did any of the out of specification product go to the public?

A I don't know.

Q Did any of the out of specification product go to Robin White?

A I don't know.

Q And you say that "OOS results must be investigated and a failure investigation is required to try to determine the cause?"

A Yes.

Q What standards are you relying on to give that

opinion?
A Safety.
Q Is there a place where I can find these safety standards written down somewhere?
A Yes, under the GMP's. It's a safety portion of the GMP's, in that, if, for example, you get an OOS result, the reason you have to do an investigation is to find out what happened so that it doesn't happen again and affect future batches or to determine whether it's happened before.
Q You say that's based on safety standards?
A Yes.

Q My question is, is there some place I can go to find where these safety standards are written down?
A Yes, you can look in the drug GMP's.
Q How about the dietary supplement GMP's?
A They don't list the safety features.
Q Thank you.
A But they were allowed to set their own standard, and the standard they set, they don't meet.
Q How many times does the Alpine manufacturing facility test each batch of their product?
A I'm sorry?
Q How many times does the Alpine manufacturing facility test each batch of their product?
A I don't know that they do.
Q How many times is it tested by HPLC?

A I would assume any time it was tested. That's the method they use.
Q You talk on page 7 of your report about reworks of finished product batches, and you state in there, "it was the policy of Metabolife to allow remanufacture of the batch of caplets."
A Caplets, yes.
Q Caplets. From where did you determine this policy?
A From the depositions.
Q From Mr. Brady's and Mr. Aschmoneit's depositions?

A Mr. Brady's, certainly, and I think Mr. Aschmoneit's.
Q Mr. Brady talked about a rework of a couple of batches from two different manufacturers, right?
A Yes.
Q Do we know if that rework product ever got to the public?
A I don't know.
Q Are you aware of there being any other specific instances of reworking of product?
A Aschmoneit did say that that was one of the procedures. They sent it back to the manufacturers for rework if it didn't pass the second time.
Q Were the rework products subject to a lesser quality control checks than the original product?
A Since they had no written procedure, I couldn't

tell.
Q How does reworking of product increase the chances for contamination?
A They were ground up in a Fitz mill, and since the Fitz mill wasn't verified as being clean, you could have got contamination as a result of that interacting.
Q Let me just stop you there. Your testimony about the Fitz mill not being clean relates to Jeff Brady's inspection of the IHP facility in Florida, correct?

A Yes.
Q Are you aware of whether IHP at that time was, in fact, manufacturing Metabolife 356?
A I don't know.
Q Okay. Go ahead. I'm sorry to have interrupted.
A Basically, reworking tablets from the finished product is going to be hard to get the particle size, you can't be sure how good the tablets are going to be from a cut-up, ground-up bunch of tablets, and it's a terrible practice, reworking at that stage. You might rework if you had a couple of things in a liquid and you had to refilter it, although, that's frowned upon, too. But to go from the finished product back, and then add other ingredients to it, to either bring it up to potency or bring it down within the potency range, is a very, very dangerous practice.
Q You indicated in your report, "While reworks are sometimes permitted by FDA," so it's not a totally taboo

subject, correct?
A No, it's not, but FDA requires a written procedure, which they didn't have, and it requires very good verification that everything went okay.
Q And when you're talking about what the FDA requires, are you referring again to pharmaceutical products?

A Yes.
Q Are you aware that the FDA's proposed new rule regarding dietary supplement manufacturers permits reworking or reprocessing of a batch which deviates from a master record?
A No. I am aware that they will allow reworks, but they require it to be in writing and well controlled, and at only certain stages. I'm sure they wouldn't approve it at the finished product stage. I've seen companies try to do that, at the finished product stage, and FDA said, no.
Q And in that instance, that would be with regard to pharmaceutical products, right?
A The ones that I'm talking about, yes.
Q And you say that the process of reworking is labor intensive and costly?
A Yes.
Q Isn't that the choice of the company?
A Yes, I just put it in as a gratuitous comment.
Q And that doesn't affect purity or safety?

A No, it shouldn't.
Q You talk about adverse reactions reporting. Where did you learn that there were thousands of complaints of adverse reactions?
A In one of the depositions.
Q Did you review any of those complaints?

A No, that's not in my area.
Q And you said there was no plan to investigate these reports even though this was recommended to them by the FDA and other scientists?
A Yes, there was a letter from a man at FDA recommending that they cooperate more fully with FDA, and the industry and FDA work together for adverse reaction reporting.
Q Is that the letter where they encourage them to report to the FDA?
A Yes.
Q That doesn't have anything to do with Metabolife's plan to investigate them, does it?
A I don't know.
Q Do you know, at that time, the number of people that the FDA had set aside to review adverse reaction reports from dietary supplements?
A No, I don't know.
Q Do you have any idea of what kind of computer system the FDA had at that point in time to utilize with regard to reviewing adverse event reports for dietary

supplements?
A No, I'm not aware at all.
Q Other than this letter that you're talking about, are there any other requirements for a dietary supplement

to investigate adverse reaction reports?
A I don't know. Wait a minute. Yes, I do. I'm sorry. I correct my answer. They got some advice from some of their own consultants. Metabolife's own consultants recommended that they do a better job of reporting adverse reactions in Brown's deposition.
Q What consultants were they?
A I don't remember their names.
Q And this is something that you say that David Brown testified about?
A Yes.
Q Those are the only other scientists that you're relying upon or referring to?
A As far as I know, yes.
Q You then say, "This product contained pharmacologically active amounts of ephedra alkaloids and caffeine, which would likely cause serious side effects." Upon what is that statement based?
A I'm sorry, I didn't hear it all.
MS. ABARAY: Is that buzzing bothering you from the --
THE DEPONENT: Yes, it's bothering my

hearing aids.

MS. ABARAY: Let me try to turn it down.

BY MR. ERNY: (Resuming)

Q If you look at page 7, and look at the very last sentence, do you see that sentence there?

A Yes, I see it.

Q Upon what is that sentence based?

A Based on what the consultants told.

Q What consultants?

A The consultants that were reviewing the adverse reactions. That's where I picked it up.

Q Is this something that was attached as an exhibit to Mr. Brown's deposition?

A I think that that was a misprint, too. It should be could likely, rather than would likely, as I recall, because that was my opinion.

Q Please understand, I'm not trying to pick on you or anything, but that's an error in your report. Instead of saying, which would likely cause serious side effects, it should be changed to say, which could?

A Yes.

Q You're not offering an opinion that Metabolife 356 causes serious side effects, are you?

A No, only in that there were adverse reaction reports, and that is a therapeutic amount of ephedra. It's not subtherapeutic.

Q Do you know whether ephedrine is approved as safe

and effective as an over-the-counter bronchodilator?

A No, I don't know. It may be. I don't know.
Q Would it surprise you to learn that the FDA approved directions for the use of ephedrine as a bronchodilator, that provides for an oral dosage of 12.5 to 25 milligrams every four hours, not to exceed 150 milligrams in any 24-hour period?
A I don't know.
Q Well, would it surprise you to learn that?
A Yes, it would, because I think ephedrine's pretty toxic.
Q In fact, if those directions provided that those dosages could be used even in children 12 and 13 years of age and older, would that surprise you?
A It certainly would.
Q When you refer to serious side effects in your report relating to adverse reactions, what do you mean by that?
A I mean the ones listed in USP and in toxicology books.
Q Can you give me some examples of serious side effects.
A Yes, anything that raises blood pressure, I think, is serious. Palpitations, serious. Stroke is mentioned as a possibility. The psychotropic effects, irritability and beyond. There's a whole number of them.

Q Does caffeine raise blood pressure?
A No, I'm talking about ephedra.
Q I'm switching gears on you. Does caffeine raise blood pressure?
A I'm not sure, I'm not sure.
Q Is it your opinion that Metabolife had a duty to investigate adverse reactions?
A Oh, yes. I think that any company that puts out a product and has adverse reactions should be looking into it, yes.
Q What should it have done?
A It should have followed up to see. There's an area called complaint files which are used in the food industry, the drug industry and so forth, complaint files telling you about complaints. It might be a complaint that the tablet won't dissolve. It's like a rock. Or the tablet breaks apart before I can take. Or it might be, I suddenly noticed that my blood pressure shot up, because I have my own home cuff, so it could be of all types. It could be the material precipitated or changed color. There's a whole bunch of things. They call them complaint files. Part of that is adverse reaction files. The complaint files, FDA requires you, for reasons of safety, again, to follow-up to see what happened, if it is a legitimate complaint or a non-legitimate complaint.

Q Let me try to break this down, so I can understand it better. We talk about complaint files, and what I sense you're saying is there are two categories of complaint files. There's one set of complaint files that actually address the physical qualities, if you will, of the product, like the tablet breaks apart, the liquid precipitates, and things like that. And your testimony is the FDA requires the company to investigate those types of complaints. I would assume that that's to see if there was a problem in the manufacture of that product to cause it to do what it is not intended to do?

MS. ABARAY: Object. I'm not sure that was his testimony.

MR. ERNY: Well, that's why I'm asking him.

A No, basically, they don't keep the files separately. They bring in all of the complaints, which could include adverse reactions. Adverse reactions may be reported from other sources to the federal government directly -- hospitals, health professionals, and so forth. When the company gets adverse reactions, they should be sharing those with FDA, so that you can see if there's a trend of these. If you distributed to, we'll say, a million people, and you only got one complaint, then it probably wouldn't be enough to require you to do much further.

Q You say that the company should share these with the FDA?
A Yes.
Q What regulation can you point to that requires that a dietary supplement manufacturer to share these complaints with the FDA?
MS. ABARAY: I think it's asked and answered that there aren't regs on dietary supplements.
Q So you're referring to when they should about the practices with pharmaceutical products?
A No. I think they should do it for foods, if they're having a problem. If they're getting adverse reactions from a food, it might be due to salmonella or something like that. I think they should do it for dietary supplements or any product that's going to be ingested.
Q Would you agree that a dietary supplement company has no power to compel someone to turn over their medical records or even discuss their medical condition?
A I think the same thing is true on the pharmaceutical side.
Q Right, right, and a pharmaceutical company or a dietary supplement company has no legal power, if you willed it, to require a physician to give information about an adverse reaction report?

A No, but they can obtain it.
Q They can obtain?
A They can obtain the power to do it. If the individual agrees to let them do it.
Q That's right, but if they don't, the companies have no power to get this stuff?
A I don't know the legal aspects of subpoenas and so forth, so I can't say.
Q Does the FDA have a specific consumer complaint form or adverse reaction form that is to be used by dietary supplement manufacturers?
A I don't know.
Q Is a reporting of adverse reactions by clinicians or physicians or patients required anywhere?
A Is it required?
Q Yes, it is required anywhere by any regulation?
A I don't know, but it's a good practice.
Q And if adverse reaction reports for dietary supplements are sent to the FDA, what division of the FDA or what group in the FDA would actually receive them?
A There's an office that receives them. I can't remember the name of it. I've been there, but I can't remember the name of it. They have a special section that deals with those kind of issues.
Q Do you have any expertise in determining whether an

individual adverse reaction report that is observed was

actually caused by a drug or a substance?

A Caused what?

Q Caused by a drug or a substance?

A I'm not sure I understand what you mean.

Q Do you consider that you have any expertise in the field of determining whether an individual adverse reaction report observed was actually caused by the substance in the adverse reaction report?

A No, I don't have any training in that area.

Q Do you know if it's possible to derive scientifically reliable estimates of the incidents of occurrence of adverse reactions from adverse reaction reports?

A I don't know.

Q Is there any specific rule or requirement or regulation in any of the FDA documents, that you're aware of, relating to dietary supplements which you could rely upon to state that Metabolife violated its duty with regard to adverse reaction reporting?

A Well, I would say from a safety point of view, they didn't do a good job of it, but that's all I can say.

Q In the adverse reaction reporting section of your report, you refer to a short term clinical study. Do you see that at the top of page 8?

A Yes.

Q What study are you talking about there?

A I believe it's the one -- Boozer. That was

Boozer's.
Q The Boozer eight week study?
A I think so.
Q Have you actually reviewed the Boozer eight week study?
A I looked at the number drop offs and the percentage of drop offs.
Q From where did you get that information?
A From the Boozer deposition.
Q Where did you get that information in writing this report?
A It was mentioned in one of the depositions, which would be the only place I could see it.
Q Did you actually review the published study that you're referring to here?
A No.
Q In what way does the fact that 8 of 35 patients receiving Metabolife 356 and dropping out of a clinical study -- how does that impact on your opinions about adverse reactions reporting?
A Well, because a good portion of the ones that dropped out had adverse reactions. That was the reason

they dropped out, according to the depositions.
Q Did any of those people have strokes?
A I don't know. I can't recall.
Q Did any of those people have seizures?

A I don't recall what they had, but they said that they had adverse reactions.
Q And adverse reactions could mean any number of things, couldn't they?
A Yes.
MS. ABARAY: Do you want to take another break?
THE DEPONENT: Yes, maybe -- if we could take five minutes.
MS. ABARAY: It's been about an hour.
(Whereupon, there was a brief recess.)
BY MR. ERNY: (Resuming)
Q Dr. Gerraughty, I want to continue on with your report. On page 8, you refer to lead contamination. Do you see that there?
A Yes, I do.
Q And you say, "Hauser Laboratories found lead in at least 3 batches of Product 356."
A Right.
Q Do you recall what year or what time frame that was?

A It wasn't well labeled. Some of the materials were not well labeled. No, I don't. I don't recall which year it was.
MR. ERNY: Off the record.
(Whereupon, there was a discussion off the record.)

BY MR. ERNY: (Resuming)
Q Dr. Gerraughty, I'm going to walk over and show you Exhibit 15 to the deposition of Dirk Aschmoneit, and it's hard to read, but you see this last column that talks about lead milligrams per caplet?
A Yes.
Q And there's in there three references to 0.01 milligrams of lead being found in three samples?
A Right.
Q Is this the document that you were referring to in your report?
A It's this document plus the testimony of Aschmoneit in his deposition.
Q Fair enough. And this is dated April 27, 1999?
A That's correct.
Q Are you aware of there being any other instances where testing of Metabolife 356 revealed the presence of lead?
A No.

Q Is 0.01 milligrams per caplet a large amount of lead?
A No, but there shouldn't be any in there.
Q I understand that, but is it a large amount of lead?
A You don't need much lead to have a problem, because it's cumulative. It stays in the body for long periods of

time. That's why they made some changes in the pain industry.

Q And you say, in fact, in your report, it "could have serious implications in long term use?"

A That's what I meant. That it would build up.

Q That's suggests to me that in the short term use, it wouldn't have serious implications?

A Probably not, if there's a one time occurrence or two time occurrence.

Q Other than these three instances, are you aware of any other testing results revealing the presence of lead?

A No, I'm not.

Q Do you know if these three lots were sent to the public?

A I don't know.

Q The next section of your report refers to spiking with synthetic components, and it refers to synthetic caffeine, correct?

A That's correct.

Q And we've talked about that a little bit before, but you say that there wasn't proper labeling, "making it impossible for the users of these products to detect." What, if anything, did you look at or inquire into to determine whether this would have mattered in any way to Robin White?

A To Robin White, nothing.

Q Or any of the other plaintiffs that you've issued

the report in.
A No, I don't know who they are.
Q In fact, you really haven't reviewed any plaintiff specific materials?
A Any what?
Q Plaintiff specific materials. For example, have you reviewed the deposition of Robin White?
A No.
Q Do you know anything at all about Robin White?
A No, other than what was mentioned in depositions.
Q Do you know anything at all about any of the other Ohio plaintiffs?
A I don't know. I don't think so.
Q Are you going to offer any opinions as it relates to these specific plaintiffs in these cases?
A No, I don't expect to.

MS. ABARAY: He's going to offer general opinions about manufacturing, which could then relate to a specific plaintiff, but he's not offering specific plaintiff testimony.
MR. ERNY: All right. I needed to find that out, because of his use of the term, "making it impossible for the users of these products to detect." I thought we were getting close to case specific, and I just wanted to make sure that we weren't.

MS. ABARAY: I think he's saying users in the general sense.

BY MR. ERNY: (Resuming)

Q Let me follow up on that. Do you have any opinions that the adding of synthetic caffeine to Metabolife 356 would have mattered to any individual taking the product?

A That's a pretty broad question. I do think it would matter to somebody who wants all natural sources, wants only to ingest things of natural sources, but I don't know in the case of the plaintiffs, who was and who wasn't. I think it would make a difference to somebody who doesn't want to have any synthetic things in their diet.

Q That's your feeling?

A Yes, my opinion.

Q Your opinion?

A Yes.

Q You also talk about, in the next section, the poor control of contract manufacturers and contract laboratories. In particular, you talk about the President/CEO, who is Mr. Brown, being "uninformed about many practices at the contract manufacturers and Hauser Laboratories."

A Yes.

Q What were the dates of the lab reports that you reviewed. We know, for example, the one we just looked at was 1999, right?

A Right.
Q What general time frame were these lab reports in?
A I can't give you a specific time frame, but I can tell you that they should be controlling any contract manufacturer or any contract laboratory that's doing work for them. They begin to do it, apparently, when what's his name, Jeff Brady, but Aschmoneit said they weren't doing it before, and he gave no evidence of them having done it before.
Q When you say "they" you're referring to Metabolife generically?
A Yes.
Q Do you know when it was that Mr. Brown became

President of Metabolife?
A I read it, but I don't remember.
Q Do you expect the President and CEO to know all the intimate details of manufacturing?
A No, but I don't think this is an intimate detail. I think it's an important issue.
Q What detail are you talking about?
A I'm talking about the fact -- what are the practices at the contract manufacturer? Does he have the proper equipment to do the job? Do they have proper laboratory procedures? Have they validated any of the steps so that they can duplicate it from time to time? Is it clean? Is it well lighted? Are the people trained who

are doing the job, a lot of things.

MS. ABARAY: Before you move on, I wanted to object to the form of the question, because he said it wasn't a detail and you called it a detail.

Q Are you telling me that you expect the President and the CEO of the company to have knowledge of all of that?

A Yes, when they're using contract manufacturers.

Q Are you telling me that in your prior consultancies with, for example, pharmaceutical companies, like, for example, the President and CEO of Abbott Laboratories has that knowledge?

A Yes, he has it available to him.

Q That's a different issue. Does he have that knowledge? I understand it may be available to him, but you're saying in here that the President and CEO was uninformed about it, and therefore, didn't have the knowledge, and having it available is two different things.

MS. ABARAY: Wait a minute. You're arguing with the witness. Let's let him answer.

A The product manager, also, was uninformed.

Q I understand. My questions are related to the President and the CEO. What I hear you saying now is he should have this information available to him? Do you know whether Mr. Brown had this information available to him?

A He said he didn't.
Q He said he didn't have this information available to him?
A He said he had never looked at this information, and he said that he didn't know whether it was available or not.
Q And you believe that's what he testified to in his deposition?
A Yes.
Q Is it uncommon for a President or CEO to delegate

responsibility to other employees?
A Yes, it is.
Q You don't have a problem with that happening?
A No.
Q You then say in your report that "outside contractors are inspected by the contracting company who should monitor these contractors frequently and carefully." What industry are you relying upon to make that statement?
A It's a practice in the industry.
Q What industry?
A In the food industry, in the drug industry, any of the industries.
Q On the last page of your report you provide a summary, at least that's what you call it, that "Metabolife International Inc. has poor control of Product

356. There are several major deficiencies in their manufacturing practices that jeopardize the safety and purity of this product." Is it your testimony that the product, Metabolife 356, produces and sells to the public is impure?

A It could be.

Q And it also could not be?

A Yes.

Q And that it's unsafe?

A I believe it is.

Q Why is it that you believe it is unsafe?

A Because they don't follow any kind of good practices. They set specifications, and they set them, not FDA. They set specifications, and then fail to meet them. Why do you need specifications if you're not going to meet them. They don't have good SOP's. There are gaps in SOP's. There's no written SOP for how to handle reworks, and several other things mentioned throughout these depositions, and I don't think they are monitoring contract manufacturers. Go through the whole litany. They're not doing a good job of controlling their product.

Q Have you tested any product that made it to the public to determine whether it's been out of spec?

A No.

Q To determine whether it contains lead?

A Whether it what?

Q Contains lead.

A No.
Q To determine whether it contains --
MS. ABARAY: He hasn't tested any product.
Q So you don't know if any product that actually got to the public suffered from any of these problems that you're talking about?
A I don't know whether the products get to the public

or not.
Q When you were talking about Jeff Brady, you mentioned that Dr. Dash made no notes during his audits and provided no written report to them?
A That's what Brady said.
Q Tell me what happens when the FDA comes and audits your facility?
A You want me to walk through what they do?
Q Yes.
A If they're coming in for a drug audit, let's say -- do you want me to do a drug audit?
Q That's fine, whatever you're more comfortable with.
A They'll hand the responsible individual, the highest responsible individual, if the CEO was there, they'd hand it to him, a 482, Notice of Inspection.
Q That just means, hey, here it is, we're coming on board, let us in?
A Yes, that's right, and of course, they usually let them in. They get inside. They have a team, usually.

It's not just one person, but occasionally, it's one person. They have a team, and they begin an audit of the plant. How they do it varies a lot from investigator to investigator, but essentially, they cover all of the same things in the long run, maybe not, if they didn't do a good job. Basically, what they do is, they inspect the

plant and the records of the plant, section by section by section, unless it's a limited inspection. It could be a limited inspection, just to pick up samples or something of that nature. Then, they go through the plant. Usually, most investigation teams, will let management know during the audit what's going on, what they're finding and so forth, but they don't have to.

Q How long does an audit take?

A It can take anywhere from an hour, picking up a sample, to weeks. Some are very long. It depends on the size of the plant, the complexity of the plant. Then, basically, at the end, they meet with management. They let the CEO decide who he wants to sit in this exit meeting, and they issue a form 483, which is a list of what they observed to be deficiencies, although it's not a total list. There's a proviso on there that these may not represent all of the objectionable conditions.

Q Let me interrupt right there. What happens if after an FDA inspection they don't find any objectionable conditions?

A I would say that's very rare that they find none,

absolutely none, but if they don't, they would probably say to the firm orally, you're okay, you're in essential compliance with GMP's.

Q So they wouldn't give you a 483 then, right?

A They might. They might give you a 483 which says, we find these two or three things, but we consider them to be minor and that the plant is in essential compliance with GMP's, maybe right on the 483.

Q But if they found absolutely nothing wrong, hypothetically, would they issue a 483?

A No, they probably wouldn't.

Q Okay, go ahead. I'm sorry.

A Then, from there on, usually they leave. The firm can call the office, the central office that they worked out of, whatever district it was, and they usually submit a response to the 483. If there are any items on the 483, they issue a response telling their side of the issue. At the exit interview, they can ask any questions. They can say, we don't agree with you, to the investigators. A lot of things can happen, but that's essentially the process, and then, of course, they may do a follow-up inspection.

Q FDA might?

A Might.

Q Do you know if, when Dr. Dash audited the Alpine Labs he found anything wrong with their procedures?

A If he found anything wrong?

Q Yes.
A Yes, I think he found a couple of things, but they were fairly minor.

Q What do you recall those being?
A I don't recall what they were.
Q If he found nothing wrong, then there wouldn't be a problem with him not giving a written report, correct?
A Yes, I think there would be a problem. I think that if he found nothing wrong, verbally, he should give a written report saying, hey, everything's okay.
Q Didn't you just say that when the FDA does it, if they find absolutely nothing wrong, they may not leave a 483?
A They may not, but they will issue what they call an EIR later, usually, establishment inspection report. They may discuss some of the issues and why they didn't consider them to be serious and so forth.
Q Is the EIR, then, provided to the company?
A Not automatically, but they usually ask for it.
Q You had indicated when the FDA folks come on board and do their audit, I think your words were, they usually find at least something at a plant?
A Yes.
Q It would be extremely rare not to find anything?
A Yes.
Q So then, you would agree that even as to pharmaceutical companies, each of those would make errors?

A Each of what?

Q Each of those companies would make errors. They would be found by the FDA?
A Not necessarily. I mean, it's a spot in time, and they might miss some things. I've been in the position of going in just before FDA or just after FDA and our two reports found some different things than the other one did.
Q So it's not uncommon for there to be some disagreement about what they find or whether it's really applicable or whether it's really a problem?
A Oh, there usually is some disagreement.
Q There's nothing wrong with that. That's pretty much standard?
A It's standard.
Q You also talked about in Mr. Brady's deposition that the FDA found that six lots of product were formulated with rejected material?
A Yes.
Q Mr. Brady testified that actually Alpine found that before the FDA did?
A Yes.
Q There's no evidence that that was shipped out at all?
A I don't know whether it was or not.
Q There's no evidence that that was Metabolife 356?

A No, I don't think it was Metabolife 356.
Q Do you know if the Chemins manufacturing facilities had ever been audited by the FDA?
A I don't think they had. I didn't see any evidence of it.
Q Have you reviewed any of the standard operation procedures for Chemins?
A For?
Q For Chemins Company?
A No, only references to them in the depositions.
Q And you're talking about the actual testimony in the depositions?
A Yes. Some of them -- I couldn't have reviewed it, because they said they didn't have one.
MS. ABARAY: Just to be clear, we did ask for all of the FDA inspection reports from Metabolife.
MR. ERNY: I understand, and I'm talking about standard operating procedures, SOP's.
BY MR. ERNY: (Resuming)
Q Let me make sure that there's no confusion here. Did you review any Chemins Company standard operating procedures documents?
A No, I didn't even see them.
Q Do you have any opinions on the manufacturing

processes at the Chemins Company?
A Yes, only from what I read in the deposition.
Q Tell me about those opinions.
A Basically, they would rework if they failed two consecutive tests. They did not have, according to either Aschmoneit or Jeff, they didn't have a rework SOP.
Q And you're referring to the Chemins Company now?
A I believe I am. I think that's what he said it was.
Q Any other opinions about the Chemins Company?
A No, except several of the lots that failed, that were outside specs --
Q In the documents that you reviewed?
MS. ABARAY: Wait, he didn't finish his sentence.
MR. ERNY: I'm sorry.
A Basically, they didn't catch those. They didn't do anything with those.
Q The outside labs caught those?
A The outside labs caught those.
Q And again, you don't know whether they were shipped out to the public or not?
A I don't know what the final distribution was.
Q I'm looking at the notes that you made of the deposition of Carol Boozer, and you say in here that there

was little in there to do with GMP's?
A Yes.
Q And you didn't read the entire deposition?
A No, I skipped over parts of it.
Q Do you believe that Mr. Brady is unqualified to do the QA or QC job at Alpine?
A Based on what he said in his deposition, yes, I do.
Q You have a letter in your file to Ms. Abaray about some previous depositions, and I assume that you've been deposed on a number of occasions?
A Yes, I have. She asked me for that listing.
Q I understand. Have any of those depositions involved dietary supplement manufacturers?
A Can I see the thing, again. It's been a while since I wrote it.
Q The letter that I'm giving you refers to only depositions in the last four years. My question is a little bit more broad than that.
A Yes, I've done several over the years.
Q Have any of those depositions involved dietary supplements?
A I'm sure they did in terms of him asking me questions about that portion of the company's business or the company's business.
Q Do you recall any of those depositions?

A No, it's been too long. These didn't involve dietary supplements.
Q Okay.
MS. ABARAY: Let the record reflect he was referring to that letter when he said "these," the one that's in the last four years.
MR. ERNY: Just so that the record's clear, he's referring to his October 17, 2002 letter.
BY MR. ERNY: (Resuming)
Q Attached to your CV, which is I believe Exhibit 1, the last page of this, Dr. Gerraughty, has a schedule of consulting fees?
A Yes.
Q I note in your file that there's a letter to Ms. Abaray dated October 16th, indicating you're only going to charge her $200 per hour or $1,600 per day, if necessary, for travel days and court days?
A Yes.
Q So would it be accurate to say that the correct statement of your schedule of consulting fees is contained in this October 16th letter, as opposed to the schedule that's attached to your CV?
A I agreed to work for $200 an hour.
Q Why the reduction in fees?
A Because it's a class-action suit, and I change my

fees based on -- I can't charge as much to the federal

government in my work for them. They have limits. If it's somebody I know, like Janet who I've worked with before, I tend to give them a break. In class-action suits, I realize that you get more money than the other people do, so I reduce my fee, and it's a standard practice if I'm doing a class-action.

MS. ABARAY: He's saying class-action in the sense of mass torte.

BY MR. ERNY: (Resuming)

Q Do you believe that the cases that you're testifying in now is a class-action?

A Well, I thought it was.

Q How much time have you spent on these cases?

A I can't tell you the total, because my current log of time -- I submitted one bill already. That was for $3,400 for 17 hours, and I've got more hours since that time. I keep a log of time, which I send to clients, along with the invoice.

Q Would there be any problem with providing me a copy of that log of time?

A I guess I could. It's up to them. I submitted it to them.

Q Would you, in addition to this list of other materials that you have at home, could you supply the

first bill that you sent to Ms. Abaray and the log of your time that you've kept since you sent out the first bill?

A It would be handwritten up to now, is that okay?

Q That's fine. I can read your handwriting pretty well.
A Okay, I can't use the computer, because of eye problems.
Q What eye problems do you have?
A I'm losing my sight. I've almost lost it in my left eye, and I'm gradually losing it in my right eye.
Q Is it like macular degeneration?
A I had cataracts removed, and the right eye came out okay, and the left eye didn't quite do as well.
Q I'm sorry to hear that.
A At least I got one good one.
Q Do you know how much additional time you've spent in this case since you sent that first $3,400 bill?
A I'd be guessing. Is that okay?
Q Give me your best guesstimate?
A Okay, six or seven more hours.
Q And that would involve?
A I've reviewed some other materials that I didn't have by the time I submitted the other bill, and I reviewed some things before I came here today.
Q What did you review before you came here?

A I looked at a couple of the depositions that were particularly key to reaching my opinions.
Q To kind of refresh your recollection?
A Yes, just to refresh it a little bit.

Q The first bill that you sent for $3,400, did that also include the time you spent reviewing Jeff Brady's deposition?

A I'm not sure. You can tell from the log of time when I send it.

MS. ABARAY: I don't think it did.

THE DEPONENT: I don't think it did, either, but I'm not sure.

MR. ERNY: Can we take a quick break and let me go over my notes? I think we can maybe wrap this up.

MS. ABARAY: Sure.

(Whereupon, there was a brief recess.)

BY MR. ERNY: (Resuming)

Q Dr. Gerraughty, other than what we've talked about today with regard to your opinions in this case, and I'm talking about the report that you've given us and the additional opinions that you've reached after your review of Jeff Brady's deposition and the review of these other documents, are there any opinions that you have that we haven't talked about today?

A Not that I can recall.

MR. ERNY: I think that's all I have. Thank you. I appreciate your time. Do you want to review and sign?

MS. ABARAY: Yes.

THE DEPONENT: What are we going to do about

my folder. Is he going to take it and get it back to me?

MR. ERNY: We can go off the record.

(Whereupon, the deposition was concluded at approximately 11:50 a.m.)

C E R T I F I C A T E

STATE OF ARKANSAS)
) ss
COUNTY OF WASHINGTON)

I, Blake Greenway, Arkansas Certified Court Reporter Number 512, a notary public in and for the aforesaid county and state, do hereby certify that the witness, Robert J. Gerraughty, was duly sworn by me prior to the taking of testimony as to the truth of the matters attested to and

contained therein; that the testimony of said witness was taken by me and was thereafter reduced to typewritten form by me or under my direction and supervision; that the foregoing transcript is a true and accurate record of the testimony given to the best of my understanding and ability.

I FURTHER CERTIFY that I am neither counsel for, related to, nor employed by any of the parties to the action in which this proceeding was taken; and, further, that I am not a relative or employee of any attorney or counsel employed by the parties hereto, nor financially interested, or otherwise, in the outcome of this action; and that I have no contract with the parties, attorneys, or persons with an interest in the action that affects or has a substantial tendency to affect impartiality, that requires me to relinquish control of an original deposition transcript or copies of the transcript before it is certified and delivered to the custodial attorney, or that requires me to provide any service not made available to all parties to the action.

Blake Greenway
Certificate Number 512

My Commission Expires:
October 25, 2005

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